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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,144	06/08/2001	David Hung	05284.00092	6700

22907 7590 11/05/2003

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	15

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/876,144	HUNG ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-10 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-10 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed August 19, 2003 have been received and entered into the application. Any rejection of record not addressed herein is withdrawn.

Response to Arguments

Applicants' arguments filed August 19, 2003 have been fully considered but they are not persuasive. Applicants argue that Claim 8 has not been rejected in the outstanding Office Action and allege that claim 8 is allowable over the prior art. This is not persuasive because on the cover sheet of the last Office Action indicates that claim 8 is rejected and on the last page of the previous Office Action also indicates "none of the claims are allowed". Further, it is clear that claim 6 is rejected and claim 8 is dependent on claim 6 and the limitation of claim 8 is specified in the rejection of claim 6. Applicants had sufficient time to make a telephone call to the examiner to clarify this matter. Applicants argue that the patent of Keller does not discuss (1) the application of the prolactin to a breast duct or (2) a ductal access tool for introducing the prolactin calibrator into a breast duct and therefore the patent to Keller cannot anticipate the amended claims 6 and 7. This is not persuasive because Keller et al. teach a stable composition comprising Applicants' lactation-stimulating agent, prolactin, comprising dye particles in an aqueous solution and because Collier et al. teach that prolactin composition can be infused intraductally using a blunt tip syringe to enhance the growth of mammary gland of a cow. It is noted that there is no physical difference in prior art of

"a blunt tip syringe" and Applicant's limitation of " a ductal access tool". Therefore, it would have been obvious that prior art of " a blunt tip syringe" to utilized intraductally to a mammary gland of a cow would obtain a ductal fluid sample including ductal epithelial cells from within a breast duct without the physical differences in the tools. Applicants further argue that Collier teaches using a blunt syringe in the administration of an agent into the teat cistern of a cow, it does not teach an instrument that can be introduced into the breast duct of a human and retrieve ductal fluid cells from within the breast duct. This is not persuasive because the introduction into a human is an intended use that does not represent a patentable limitation since such fails to impart any physical limitation to the tool utilized by Collier. Applicants argue that Tabar also like the patent to Collier, is not concerned with obtaining ductal fluids, and only related to introducing fluids into a duct. This is not persuasive because again there is no difference in physical characteristics of the tool disclosed by Tabar and Applicant's tool. Therefore, it would have been obvious that prior art of "a syringe" which is obviously sized to utilize intraductal use is capable of obtaining ductal fluid sample including ductal epithelial cells as well. Applicants' disclosure of U.S.Patent No. 6,413,228 and the article published in The Lancet have been carefully considered but not persuasive. The ductal access device taught in U.S.Patent No. 6,413, 228 and the article are more specific than Applicants' claimed tool. Applicant's claimed tool is broader therefore it covers the tools (e.g. the tools taught by Collier) that are more broadly interpreted than the specific ductal access device taught in the patent therefore it is not in same scope of Applicant's

claims. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. of record in view of Collier et al of record.

Keller et al. teach on column 5, lines 45-54, teach a stable aqueous solution comprising prolactin and dye. (column 1, lines 31-33, column 5, lines 45-55). Keller et al. disclose that prolactin solutions in general are unstable. (column 2, lines 3-5).

Keller et al. do not teach the ductal access tool set forth in claims 6 and 9.

Collier et al. teach the technique comprising the intramammary infusion by using a blunt-tip syringe comprising prolactin compound for enhancing the growth of

mammary gland. (column 3, lines 45-60, column 22, lines 61-66). Collier et al. disclose that intraductal injection of lactogenic hormone (i.e. prolactin) induce lactation. (column 1, lines 51-61).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate a system comprising blunt-tip syringe (ductal access tool) comprising prolactin and dye for intramammary infusion because Collier et al. teach a technique comprising a ductal access tool (blunt tip syringe) can be used to administer a composition comprising prolactin and dye intraductally to enhance the growth of mammary gland. One would have been motivated to formulate a system comprising a ductal access tool taught by Collier et al. with keller's composition in order to achieve its beneficial effect of enhancing the growth of mammary gland and inducing lactation as taught by Collier et al.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. in view of collier et al. as applied to claims 6-7 and 9 above, and further in view of Tabar et al. of record.

Keller et al. and Collier et al as applied as before.

Keller et al. do not teach the ductal access tool being preloaded with an anesthetic solution.

Tabar et al. on page 36 middle column, teach that intraductal administration procedure is painful.

It would have been obvious to one of ordinary skill in the art to combine an anesthetic solution with Keller composition because the intramammary infusion

(intraductal administration) is painful as taught by Tabar et al. One would have been motivated to formulate a composition comprising the stable aqueous solution of Keller et al. with an analgesic agent for the technique taught by Collier et al. to reduce pain during the procedure and also for the convenience for having all the active agents in one single formulation.

Absent any evidence to the contrary, there would have been a reasonable expectation of success in using the compounds taught Keller et al. with anesthetic agent in the technique taught by Collier in one "system" to achieve expected stable and painless intramammary infusion.

Claims 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. in view of collier et al. as applied to claims 6-7 and 9 above, and further in view of Yates of record.

Keller et al. and Collier et al as applied as before.

Keller et al. do not teach the pad set forth in claim 8 and 12.

Yates teach on that gum **pad** can be used for the topical systemic delivery of a wide range of pharmaceutical agents including prolactin.

It would have been obvious to one of ordinary skill in the art to formulate a "system" comprising Keller et al.'s composition as modified by Collier together with Yates pad because the gum pad can be used for the topical systemic delivery of prolactin as taught by Yates. One would have been motivated to formulate Keller et al's composition modified by Collier together with Yates pad in a "system" to formulate topical systemic delivery of active agent prolactin to provide variety selections of various

access tools for introducing prolactin composition to mammary duct and/or to provide dual action in enlargement of mammary gland. Absent any evidence to contrary, there would have been a reasonable expectation of success in combining the composition taught by Keller et al. with the pad taught by Yates to achieve expected benefit of inducing lactation as taught by Collier for the topically delivery of active therapeutic agent, prolactin. For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

THEODORE J. CRIARES
PRIMARY EXAMINER
GROUP 1600

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
October 27, 2003